

**CHILDRENS PAIN RELIEF AND FEVER REDUCER ORAL SUSPENSION CHERRY-
acetaminophen suspension
Puro Pharma Inc.**

Children's Pain Relief & Fever Reducer Oral Suspension Cherry

Drug Facts

Active ingredient

(in each 5 mL = 1 teaspoonful)
Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses temporarily ■ reduces fever

■ relieves minor aches and pains due to:

■ the common cold ■ flu ■ headache ■ sore throat

■ toothache

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes: ■ more than 5 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Do not use

■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

■ If your child is allergic to acetaminophen or any other of the inactive ingredients in this product.

Ask a doctor before use if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

When using this product do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

■ pain gets worse or lasts more than 5 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ **this product does not contain directions or complete warnings for adult use.**

- shake well before using
- mL = milliliter; tsp = teaspoonful
- find the right dose on the chart below. If possible, use weight to dose, otherwise, use age.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor.

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2 - 3 years	5 mL (1 tsp)
36-47	4 - 5 years	7.5 mL (1 1/2 tsp)
48-59	6 - 8 years	10 mL (2 tsp)
60-71	9 - 10 years	12.5 mL (2 1/2 tsp)
72-95	11 years	15 mL (3 tsp)

*or as directed by a doctor

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- **each 5 mL (1 tsp) contains; sodium 3 mg**
- store between 20-25°C (68-77°F)
- do not refrigerate
- Keep carton for full directions for use.

Inactive ingredients anhydrous citric acid, butylparaben, FD&C red #40, flavor, glycerin, high

fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions? Call 1-877-798-5944

Package Labeling PURO PHARMA Children's Pain & Fever Acetaminophen Oral Suspension Cherry Flavor

PURO

PHARMA NDC 83474-001-04

COMPARE TO THE

ACTIVE INGREDIENT

IN CHILDREN'S TYLENOL

ORAL SUSPENSION*

PURO

PHARMA

Children's Pain & Fever

Acetaminophen

Oral Suspension

Pain reliever

Fever Reducer

- **Ibuprofen Free**
- **Aspirin Free**
- **For Ages 2 to 11**

4 FL OZ (118 mL)

160 mg per 5 mL

Cherry Flavor

This product is not manufactured or distributed by McNeil

Consumer Healthcare, distributor of Children's Tylenol[®]

Oral Suspension

Distributed by:

Puro Pharma Inc.

42 Catharine St. Poughkeepsie, NY 12601

Info@puro-pharma.com

BX-175

NO VARNISH

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

Drug Facts

Active ingredient Purpose
Acetaminophen 160 mg Pain reliever/fever reducer

Uses temporarily relieves fever relieves other aches and pains due to:
• the common cold • flu • headache • sore throat • toothache

Warnings
Liver warning
This product contains acetaminophen. Severe liver damage may occur if your child takes:
• more than 5 doses in 24 hours, which is the maximum daily amount • with other drugs containing acetaminophen
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
• skin redness • blisters • rash
If a skin reaction occurs, stop use and seek medical help right away.
Sore throat warning
If sore throat is severe, persists for more than 7 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Do not use
• with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
• if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has liver disease

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

When using this product do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if
• pain gets worse or lasts more than 5 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present.
These could be signs of a serious condition.

Keep out of reach of children.
Overdose warning:
Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (Continued)

(1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• This product does not contain directions or complete warnings for adult use.
• Always use before using:
• mL = milliliter, tsp = teaspoonful
• Find the right dose on the chart below, if possible, use weight to dose, otherwise, use age.
• If needed, repeat dose every 4 hours while symptoms last.
• Do not give more than 5 doses in 24 hours.
• Do not give for more than 5 days unless directed by a doctor.

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under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1 1/2 tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 1/2 tsp)
72-90	11 years	15 mL (3 tsp)

For as directed by a doctor.
Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

• each 5 mL (1 tsp) contains sodium 3 mg
• store between 20-25°C (68-77°F)
• do not refrigerate
• keep out of reach of children.
• Keep out of reach of children.

Inactive ingredients: anthracis citric acid, butylparaben, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and calciummethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions? Call weekdays from 9:00 AM to 4:30 PM EST at 1-877-799-6944

This Product is not manufactured or distributed by Medline Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

Distributed by:
Puro Pharma Inc.
42 Catherine St.
Peapack, NJ 07601. BX-175

P PURO PHARMA

NDC 83474-001-04

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL ORAL SUSPENSION*

Children's Pain & Fever

Acetaminophen (160 mg per 5 mL)
Oral Suspension

P PURO PHARMA

NDC 83474-001-04

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL ORAL SUSPENSION*

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Acetaminophen (160 mg per 5 mL)
Oral Suspension

Pain Reliever
Fever Reducer

- Ibuprofen Free
- Aspirin Free
- For Ages 2 to 11



4 FL OZ (118 mL)
160 mg per 5 mL

Cherry Flavor

P PURO PHARMA

NDC 83474-001-04

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NO VARNISH

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Puro PHARMA
Children's Pain & Fever
 Acetaminophen (160 mg per 5 mL)
 Oral Suspension
**Pain Reliever
 Fever Reducer**

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL ORAL SUSPENSION*

IBUPROFEN FREE
ASPIRIN FREE
FOR AGES 2 TO 11

4 FL OZ (118 mL)
 160 mg per 5 mL

Cherry Flavor



DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

Active Ingredient (In each 5 mL = 1 teaspoonful) **Purpose**
 Acetaminophen 160 mg Pain Reliever/fever reducer

Uses: temporarily ■ reduces fever ■ relieves minor aches and pains due to:
 ■ the common cold ■ flu ■ headache ■ sore throat ■ toothache

Warnings: **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes: ■ more than 5 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen **Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. **Do not use:** ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ If your child is allergic to acetaminophen or any of the inactive ingredients in this product. **Ask a doctor before use if your child has liver disease. Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin. When using this product do not exceed recommended dose (see overdose warning). Stop use and ask a doctor if** ■ pain gets worse or lasts more than 5 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occurs ■ redness or swelling is present. These could be signs of a serious condition. **Keep out of reach of children. Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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60-71	9 - 10 years	12.5 mL (2 ½ tsp)
72-95	11 years	15 mL (3 tsp)

*or as directed by a doctor

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device. **Other information:** ■ each 5 mL (1 tsp) contains: sodium 3 mg ■ store between 20-25°C (68-77°F) ■ do not refrigerate. **Inactive ingredients:** anhydrous citric acid, butylparaben, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions? Call 1-877-798-5944 **Lot:**

Distributed by: Puro Pharma Inc.
 Poughkeepsie, NY 12601 **LR-199** **Exp:**

res

CHILDRENS PAIN RELIEF AND FEVER REDUCER ORAL SUSPENSION CHERRY

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83474-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83474-001-04	1 in 1 CARTON	03/28/2024	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/28/2024	

Labeler - Puro Pharma Inc. (128518845)

